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| 7590 07/01/2008 Benton S. Duffett, Jr. BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404 | | | | |
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/879,117
Filing Date: June 13, 2001
Appellant(s): WANSELIN ET AL.

Wendi L. Weinstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 06/12/2007 appealing from the Office action mailed on 12/14/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|-------------------|---------|
| 3,407,027 | Huston | 5-1964 |
| 4,764,351 | Hennebert et al. | 8-1988 |
| 4,919,888 | Spence | 4-1990 |
| 4,165,404 | Quehl | 8-1979 |
| 5,837,181 | Leimbacher et al. | 11-1998 |
| 5,894,014 | Houston et al. | 4-1999 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huston et al (U.S.P.N. 3,407,027) in view of Hennebert et al (U.S.P.N. 4,764,351).

Regarding claim 1, Huston discloses a sterilization chamber (figure 1:14) within an autoclave device (figure 1:10) that includes the following: a housing (figure 1:12, 15 and 17), pressure means (an autoclave device necessarily uses steam, which is the pressure means), a front planar wall surface (unlabeled planar front wall surface of chamber 14 in figure 2) that includes a front opening, a rear planar wall surface (unlabeled planar rear wall surface of chamber adjacent to housing 17 in figure 1), chamber body portion disposed between the front and the rear surfaces (unlabeled region of chamber 14 between both surfaces in figure 1), a chamber is capable of being releasably fastened within the autoclave device (figure 1:14, 28 and figure 2:14, 27, 23) such that the front (front end of chamber 14 is directly connected to 15 of the housing as shown in figure 2) and the rear wall surfaces (rear end of chamber 14 is directly connected to 17 of the housing as shown in figure 1) are directly connected to the

housing of the autoclave device (figure 1:10). Huston teaches that the inner shell (sterilization chamber) is to be manufactured from corrosion resistant material (col.1, lines 48-52), but fails to explicitly teach the type of building material. In addition, Huston fails to explicitly recite the presence of steam inlet within the wall of the chamber that is necessary for inputting steam into the chamber and the explicit presence of display means in the autoclave device.

It is known in the art to form chambers from either stainless steel or plastics. Hennebert teaches a sterilization apparatus having a chamber, and that various pressures within the chamber can be operated (col.2, lines 47-58 and col.9, lines 47-52). Hennebert further discloses the following: a chamber that is constructed of plastic material (col.5, lines 17-27, col.6, lines 53-55 and col.9, lines 10-16), a steam inlet within the wall of the chamber (figure 1:1 and 17) and the use of a thermostat that necessarily includes a display for temperature readings. As to the added limitation that "the polymeric chamber has natural heat isolating properties so as to reduce the risk of burning to a person touching the housing of the autoclave device", Hennebert's chamber is plastic which is known to be capable of having heat isolating properties so that persons touching it do not burn their hands. See MPEP 2114 where in apparatus claims, structural features limit the scope of such claims, not intended usage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the chamber of the apparatus of Huston out of polymeric material as taught by Hennebert since plastic is low in cost, does not conduct electricity (Hennebert, col.5, lines 23-25 and col.6, lines 53-54) and is corrosion resistant. It would

have been obvious to further add a thermostat to that apparatus of Huston in order to ensure that temperature within the chamber is maintained within the intended range (Hennebert, col.7, lines 67-68 and col.8, lines 1-2) so that sterilization is achieved efficiently.

Regarding claims 11-12 and 14-15, Huston teaches the following: a chamber that is capable of being releasably fastened within the autoclave device (figure 1:14, 28 and figure 2:14, 27, 23), a chamber which is essentially manufactured in one continuous piece (figure 1:14), a chamber which is sealed by a movable sealing door (figure 2:11) and a sterilization cycle (autoclaving) which is to be performed in the sterilization device (figure 1:10).

Regarding claim 13, Huston fails to explicitly recite the presence of a steam inlet within the wall of the chamber that is necessary for inputting steam into the chamber. Hennebert teaches an integral steam inlet within the wall of the chamber (figure 1:1, 17 and unlabeled integral opening in chamber for inputting steam). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further add an integral opening into the wall of Huston chamber as taught by Hennebert (figure 1:1, 17) so that steam is directly added into the space of the chamber resulting in rapidly increasing pressure and temperature within the chamber.

Claims 2, 5-6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huston et al (U.S.P.N. 3,407,027) in view of Hennebert et al (U.S.P.N. 4,764,351) as applied to claim 1 and further in view of Spence (U.S.P.N. 4,919,888)

Regarding claims 2 and 5-6, Huston and Hennebert fail to teach the following: a chamber that is manufactured from an injection-mouldable material, the injection-mouldable material essentially is a polyamide material and that the chamber is manufactured from a composite material. Spence teaches the following: a sterilization chamber that is manufactured from an injection-mouldable material (col.4, lines 36-37 and line 31), the injection-mouldable material essentially being a polyamide material (col.4, lines 36-37 and line 31) and that the chamber is manufactured from a composite material (col.4, line 31). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute construction material of Huston chamber with polymeric material as taught by Spence since such materials are not adversely affected by the sterilant or by the sterilization conditions (Spence, col.4, lines 30-33).

Regarding claim 19, Huston discloses a chamber (figure 1:14) that is capable of being releasably mounted and fastened within the autoclave device (figure 1:14, 28 and figure 2:14, 27, 23).

Claims 3-4, 7-9 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huston et al (U.S.P.N. 3,407,027) in view of Hennebert et al (U.S.P.N. 4,764,351) and Spence (U.S.P.N. 4,919,888) as applied to claims 2 and 6 and further in view of Quehl (U.S.P.N. 4,165,404).

Regarding claims 3-4, 7 and 9, Huston, Hennebert and Spence all fail to teach the following: the use of a reinforcement material such as a rowing weave, the use of carbon fiber, a concatenating polymer material such as an epoxy material and the use

of a glass fiber rowing weave. Quehl teaches the use of a reinforcement material such as rowing weave (col.2, lines 11-14 and line 45) arranged around injection mouldable material (col.7, lines 24-27 and lines 48-50), and the use of carbon fiber (col.2, line 44) and a concatenating polymer material such as an epoxy material (col.6, lines 10-12). Quehl also teach the use of glass fiber (col.2, line 44) and a concatenating polymer material (col.6, lines 10-12). Quehl teaches that all these are elements which provide reinforcement. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the constituting material of Huston chamber by including glass or carbon fibers because of their desirable physical properties as evidenced by Quehl (Quehl, col.2, lines 47-48).

Regarding claims 8 and 16-18, Huston, Hennebert and Spence all fail to teach the following: the use of a reinforcement material such as rowing weave, the use of carbon fiber and a concatenating polymer material such as an epoxy material. Quehl teaches the following: the use of a reinforcement material such as rowing weave (col.2, lines 11-14 and line 45) arranged around the injection mouldable material (col.7, lines 24-27 and lines 48-50), the use of carbon fiber (col.2, line 44) and a concatenating polymer material such as an epoxy material (col.6, lines 10-12), the use of glass fiber (col.2, line 44) and a concatenating polymer material (col.6, lines 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the constituting material of Huston chamber by including glass or carbon fibers because of their desirable physical properties as evidenced by Quehl (Quehl, col.2, lines 47-48).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huston et al (U.S.P.N. 3,407,027) in view of Hennebert et al (U.S.P.N. 4,764,351), Spence (U.S.P.N. 4,919,888) and Quehl (U.S.P.N. 4,165,404) as applied to claim 9 and further in view of Leimbacher et al (U.S.P.N. 5,837,181).

Huston, Hennebert, Spence and Quehl all fail to teach the use of specific types of concatenating polymers as recited in the claim. However, Leimbacher teaches the use of polyvinyl alcohol fibers (col.5, lines 25-26). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Huston chamber by including polyvinyl alcohol since such a fiber is known to have a high modulus as taught by Leimbacher in col.5, lines 25-26.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huston et al (U.S.P.N. 3,407,027) in view of Hennebert et al (U.S.P.N. 4,764,351) as applied to claim 14 and further in view of Houston et al (U.S.P.N. 5,894,014).

Huston and Hennebert fail to teach a chamber having a pair of integrally formed tracks in which the sealing chamber door may be slidably mounted. Houston teaches that the chamber door is slidably mounted (col.2, lines 61-64) and that the chamber door is provided with a pair of integrally formed tracks (figure 2:44) such that the tracks and the chamber are capable of being removed simultaneously. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Huston chamber door with a slidably mountable chamber door with a pair of formed tracks as taught by Houston since vertically slidable chamber door makes

loading and unloading of items into and out of the autoclave easier and safer than other types of doors.

(10) Response to Argument

B. On pages 9-10 of the brief, Appellant argues that the inner shell 14 of Huston is clearly permanently attached to the outer shell 12 through the end ring 15 at the welds 22, 23, 27, 29 and the inner shell 14 is not releasably fastened to the autoclave outer shell 12 and thus the inner shell 14 does not correspond to the sterilization chamber of claim 1. Appellant also argues that the outer shell 12, the end ring 15 and the end member 17 of Huston therefore do not correspond to the housing of claim 1; that one of ordinary skill in the art would not regard the inner shell 14 as a self supported structure, as recited in claim 1, since due to the high pressure operating conditions of the autoclave of Huston, the outer shell 12 must be present.

The inner shell 14 is capable of being releasably fastened to the autoclave outer shell 12, i.e., by breaking the welding points. There are two elements which have been joined together. Given the right tools, these two elements are "releasable." Furthermore, the sterilization chamber in Huston is the unlabeled region within chamber 14 that is enclosed between front planar wall surface (unlabeled planar front wall surface of chamber 14 in figure 2) and rear planar wall surface (unlabeled planar rear wall surface of chamber adjacent to housing 17 in figure 1). The inner shell 14, which is made of nickel clad is capable of being a self supported structure depending on the value of pressure applied within the device.

On pages 10-12 of the brief, Appellant argues that Hennebert requires that the sterilization chamber be used in formaldehyde gas sterilization; that the Hennebert sterilization apparatus relates to low temperature sterilization when objects to be sterilized cannot be subjected to elevated temperatures in conventional heat sterilization methods, i.e., cannot be sterilized in an autoclave; that Hennebert specifically teaches away from the use of its plastic sterilization chamber in a conventional high temperature autoclave apparatus as taught by Huston; that if modified as suggested by the examiner then there is no teaching or suggestion that the chamber would be able to withstand the sterilization pressures to be exerted thereon; that Hennebert further teaches that the chamber that is a plastic material is used under the requirement of subatmospheric pressure and includes embedded electrical elements; and that if Hennebert contemplated the use of a plastic chamber in an autoclave, there would be no need to include heating elements as the chamber would be heated during the sterilization process.

Appellant points to column numbers and lines for support, yet such references are either irrelevant or do not teach away from the combination. In col.1, lines 14-23, Hennebert simply shows that there are other sterilization methods for medical devices that cannot withstand high temperature. In col.5, line 22, Hennebert teaches that plastic chambers do not conduct electricity and withstand subatmospheric pressure values. In addition, see col.9, lines 19-22, where a source of steam is connected to Hennebert plastic chamber. See MPEP 2114 where in apparatus claims, structural features limit the scope of such claims not intended usage and that Hennebert plastic chamber is

capable of handling various temperatures and pressures. Therefore, Hennebert does not teach against constructing chambers made of plastic for autoclaving.

C. On page 13 of the brief, Appellant argues that the Spence container is not suitable to be used as a pressure chamber (internally pressurized) in an autoclave device, especially not according to the ASME; and that the container has only a microorganism proof seal between the lid and the base and is not adapted to be internally pressurized.

The Spence reference is combined with Huston and Hennebert for its teachings of manufacturing chambers from polyamide injection-mouldable material and composite material (col.4, lines 31 and 36-37). Spence's container is placed in an autoclave and is capable of withstanding high pressure and high temperature values (see col.2, lines 34-36 or col.6, lines 18-23).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Art Unit: 1797

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Monzer R. Chorbaji
/M. R. C./

Conferees:
/Jill Warden/, SPE
Patrick J. Ryan, SPE

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795

Wendi L. Weinstein
Buchanan Ingersoll & Rooney pc
P.O. Box 1404
Alexandria, Virginia 22313-1404